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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,313	08/18/2003	Atsuko Fukui	RYUK.001RE	4219

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/643,313

Applicant(s)

FUKUI ET AL.

Examiner

Susan T. Tran

Art Unit

1615

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) a set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-24.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

Art Unit: 1615

Advisory Action

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "packaged in a prepared form *in the absence of a medication*" in claims 1 and 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speck et al. US 5,010,061.

The patent discloses compositions comprising guar flour mixed with a corresponding volume of aqueous liquid and drink within 0-5 minutes after complete mixing (See col. 3, lines 27-31), and teaches that drugs, vitamins, minerals and all kinds of contrast media can be added to the flour (See col. 3, lines 32-51). In the examples provided, the guar flour is suspended in water and drunk soon after (See Examples 1-4), or the guar flour is mixed with a medicine or contrast agent, the mixture is suspended in water and drunk soon after (See Examples 5-8). The patent teaches that the composition can be administered orally for the treatment of diseases, including intestinal peristalsis and diabetes (col. 3, lines 32-43; and claims 1, 4-21). The patent also provides the general teaching, that indigestible polysaccharides, such as agar and guar, swell in water and form viscous jellies (See col. 1, lines 8-25).

Thus, the patent discloses drinkable compositions comprising water and a paste, which form a viscous liquid, and a medicine enwrapped in the viscous liquid, as claimed in instant claims 1, 2, 6, 7, 21 and 23, and methods for taking a medication, as claimed in instant claims 11, 13, 15, 17, 19 and 20. The patent is deficient in the sense that it does not specifically disclose the viscosity range and the gel strength of the gel, however, the patent teaches that solutions of sufficiently low viscosity can be obtained by mixing the guar with water, and said solutions can be drunk (See col. 1, lines 60-62). Furthermore, it is the position of the examiner that because the patent teaches the same ingredients and same compositions as Applicant, it would flow that the invention disclosed by the patent would have the same viscosity range and gel strength as the invention claimed by Applicant. The burden is shifted to Applicant to provide evidence

Art Unit: 1615

that the two compositions exhibit different properties, if this is the characteristic to be relied upon to show patentable distinction. Absent such an evidence, this invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

With regard to claims 3, 8, 22 and 24, the patent teaches that aqueous suspensions are preferred, in which the content of the guar flour is at least 2% (See col. 3, lines 67-68). Furthermore, Example 3 teaches that 4 grams of guar flour are suspended in 150 ml cold water and drunk rapidly. The mixture disclosed by the patent produces a solution of 2.6% guar and 97.4% water, which is in the range claimed by Applicant.

Regarding claims 4, 5, 9, 10, 12, 14, 16 and 18, the examples provided in the patent indicate that the guar flour is mixed with drugs, vitamins or contrast agents in solid form (See Examples 5-8). It is the position of the examiner that, due to the nature of the mixture disclosed by the patent, said drugs, vitamins or contrast agents are mixed in powder form, as claimed by Applicant. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Speck et al. to device drinks to help individuals swallowing a medication, and methods for administering a medication, comprising swallowing said drinks. The expected result would have been a successful drug delivery composition and successful methods for administering drugs. Because of the teachings of Speck et al., that drugs, vitamins and contrast agents can be added to guar flour, mixed with water and drink immediately, one of ordinary skill in the art would have a reasonable expectation that

Art Unit: 1615

the compositions and methods claimed in the instant application would be successful in assisting an individual in swallowing a drug. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 12/27/04 have been fully considered but they are not persuasive.

Applicant pointed to column 3, lines 35-39 for support of the limitation of the "prepared form". In view of applicant's remarks dated 12/27/04, that the product could be packaged in a small container and the like as a "prepared form", the 112, 1st paragraph rejection has been withdrawn. However, nowhere in the specification provide support for the limitation "a prepared form in the absence of a medication". Therefore, the original rejection is maintained.

Applicant argues that Speck teaches vitamins and drug are ancillary options only, there is no suggestion that guar flour can make it easier to take medicine. However, it is not necessary for the prior art show each and every property of the claimed product. The burden of proof is shifted to applicant to prove that the prior art products do not necessarily or inherently possess the characteristic (composition that makes it easier to take medicine) of the claimed product, because Speck teaches a similar composition desire by applicant, e.g., composition that contains indigestible polysaccharides, such as agar and guar, that swell in water and form viscous jellies (See col. 1, lines 8-25). *In*

Art Unit: 1615

re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). Furthermore, no criticality is seen in the particular limitation, because Speck teaches drinkable compositions comprising water and a paste, which form a viscous liquid, and a medicine enwrapped in the viscous liquid, as claimed in instant claims 1, 2, 6, 7, 21 and 23. No unusual and/or unexpected results have been shown in the use of "a prepared form" over those disclosed by Speck. Accordingly, the 103(a) rejection over Speck is maintained.

Correspondence

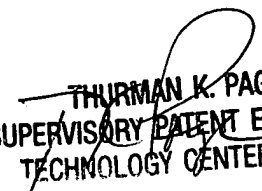
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1615

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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SUPERVISORY PATENT EXAMINER
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